UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

No. 12-md-02409-WGY
Volume 1, Pages 1 - 65

In Re: NEXIUM (ESOMEPRAZOLE)
ANTITRUST LITIGATION

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For Jury Trial Before:
Judge William G. Young

United States District Court
District of Massachusetts (Boston)
One Courthouse Way
Boston, Massachusetts 02210
Wednesday, November 12, 2014

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I N D E X

E X H I B I T S

P R O C E E D I N G S

(Begins, 9:30 a.m.)

THE COURT: Good morning. I came out before the jury because you're entitled to know the Court's ruling on the motion to strike the testimony of McCool. Let me say I've been very much aided both by the briefing and the arguments of counsel. And after full consideration I do strike so much of the testimony of McCool as comes up with his 55 percent plus 10 million upfront and also the dollar amounts of the supposed comparables. The ground for the Court's -- and it is a preliminary finding, not a ruling, entitled to deference on appeal, is that upon reflection he bases his opinion on data that is not reliable. It's not reliable because of the selection of only a portion of the potential range of possible comparables.

Now, while I strike that, I must tell you that I accept, um -- I'm not so finding but I -- well, I guess I am finding. I accept Mr. Sobol's argument that the qualitative aspects of his testimony, bolstered by the testimony of McGuire, who, without hearing, I determined the motion to strike McGuire's testimony is denied, the qualitative aspects specifically that in this unique circumstance there are no real comparables and the other qualitative aspects of his testimony stand.

I'm not saying anything to the jury this morning and I don't know that I'll have to say anything to the jury because we're moving on now to the motion for a directed verdict at this stage, and I will entertain the defense argument and 2:00 this afternoon, and once I've heard the arguments, we'll see where we stand. But you needed to know what you can base your arguments on relative to McCool and I've made my ruling.

All right. Bring the jury out.

(Pause.)

THE COURT: Just as they are coming in, we are in the midst of a deposition that has only a little time left, when we finish that, then what's going to happen?

MR. SHADOWEN: Your Honor, we're going to move the admission of a deposition transcript, or a portion of it, and then comes Mr. Jay Deshmukh.

THE COURT: Okay. Live or by --

MR. SHADOWEN: Live.

THE COURT: Fine. And is the portion of the deposition -- is this GCR?

MR. SHADOWEN: It's GDM, Mr. Diggons.

THE COURT: Do I have it? Have I vetted it?

MR. SHADOWEN: Yes, you have, your Honor.

THE COURT: Oh.

MR. SHADOWEN: These are the deposition

designations of the parties after the Court's rulings.

THE COURT: All right. Fine.

MR. SCHMIDTLEIN: Your Honor, we object -- if they want to play the video, they can play the video, but we object to just moving in --

THE COURT: Oh, I don't intend to put it in as an exhibit.

(Jury enters, 9:35 a.m.)

THE COURT: Good morning, ladies and gentlemen. Thank you so very much for your promptness. We're all ready to go. We were listening to a deposition and we'll finish that deposition.

(Resumes video of Venkatachalam Krishnan.)

Q. We are marking as Deposition Exhibit Venkat 20 a document produced to us by Ranbaxy in this case. It appears to be a letter from a law firm of Mathews, Shepherd, McKay & Bruneau dated July 19th, 2007 to the Honorable Joel A. Pisano. It's a seven-page document, Bates page RAN-ESM 244 through 250.

In the first page of that -- the first page of that letter, the first paragraph, it's noted that this letter is being submitted to Judge Pisano on behalf of Ranbaxy, Inc. and Ranbaxy Laboratories, Limited. Do you see that?

A. Ranbaxy, yes.

Q. You have no reason to believe that this law firm wasn't authorized to actually file this on behalf of Ranbaxy, do you?
A. No.
Q. I'll refer you to the last page of this exhibit. Then in the next paragraph it goes on to say that "Ranbaxy is willing to discuss a settlement that resolves the litigation by selecting an agreed-upon date for market entry of Ranbaxy's generic product wherein the agreed-upon date is a compromise between market entry in 2008 and the expiry of the 2014/2015 patents as Ranbaxy does not infringe the patents that expire in 2018 and 2020. Do you see that?
A. Yes.
Q. Do you believe that was a correct statement of Ranbaxy's settlement position as of July 19th, 2007?
A. What, the compromise?
Q. Yes, what it was willing to compromise to.
A. Yes.
Q. Now, as we know from the agreement, one of the entry dates is May 27th, 2014. Correct?
A. Correct.
Q. If available to it, do you think that Ranbaxy would have been willing to agree to an entry date prior to that?

A. That's speculation. I don't know.
Q. Would it has been palatable to Ranbaxy to agree to an entry date that was prior to May 27th, 2014?
A. Possibly, yes.
(Video ends.)
THE COURT: That's it?
MR. SOBOL: I think that's it.
THE COURT: All right.
MR. SOBOL: So the plaintiffs then move the following exhibits that were played during the videotape and to the jury in evidence. EUS. EMV. EOQ. ENS. EOZ. FJC.
THE COURT: Wait a second. ENS. EOZ. Go ahead.
MR. SOBOL: FJC. FJE. And finally DMV.
THE COURT: No objection?
MS. FOLEY: Your Honor, we have an objection. I believe the last one was DMT?
THE COURT: DMV.
MS. FOLEY: I believe the exhibit -- is that the July 19th, 2007? This is the settlement statement of Ranbaxy to the Court. We ask that it be admitted with the same limitation as other pleadings.
THE COURT: And no objections to the others?
MS. FOLEY: Yes.
THE COURT: Fine. Then EUS will be Exhibit 130.

EMV 131.

THE CLERK: Judge, 131 will be EUS.

THE COURT: Oh, thank you. I'll start again.

EUS, 131. EMV, 132. EOQ, 133. EMS, 134. EOZ, 135. FJC, 136. FJE, 137. DMV, 138, but it's limited as I've limited other things submitted to the Court for the fact, if you believe it to be a fact, that this was filed in court but not for the truth of what was said there.

(Exhibits 131 to 138, marked.)

THE COURT: Go ahead.

MR. SOBOL: Before we proceed with the next witness, your Honor, can we have a brief sidebar?

THE COURT: We may.

AT THE SIDEBAR

MR. SOBOL: It's simply a small but an important distinction. The last exhibit, Exhibit 138, is a settlement position paper by Ranbaxy. We agree completely that so much of that position paper that asserts positions regarding the merits of the case would be limited. However, there's a portion at the end of the settlement which states Ranbaxy's position vis-vis settlement and that should go in for the truth of the matter asserted because it's a statement of a party

opponent regarding what its settlement position was. It's a small distinction, but I think it's important.

THE COURT: He's right, isn't it, it's an admission?

MS. FOLEY: Yes.

MR. BALDRIDGE: Completely confusing though as to what the nuance is between the settlement position.

THE COURT: I can't help that. I will so -- just give me the specifics. Just mark it out. And I'll give an appropriate instruction.

Again, to sort of save this, if you're going to recall McGuire and I look forward to McGuire being recalled, um, I'm not letting McGuire get into payments from Ranbaxy. The question -- the only question as to Ranbaxy is whether they knew that, um, from their deal with AstraZeneca, AstraZeneca was going to pay for delay as to everyone else? In other words, did they know, when they first settled, that that was -- that AstraZeneca was going to buy out and pay for delay with respect to the others so that the jury could find that Ranbaxy conspired with AstraZeneca and Teva? I'm not interested in payments.

MR. SCHMIDTLEIN: And he has no opinion on it.

THE COURT: You just won that.

MR. SCHMIDTLEIN: Yeah, I know.

(Laughter.)

Thank you, your Honor.

(In open court.)

THE COURT: The document? I should probably give the charge now.

MR. SOBOL: May I approach, your Honor?

THE COURT: Yeah, of course.

And the paragraph is?

MR. SOBOL: Yeah, it's -- you'll see it begins on the second-to-last page, your Honor, with an obvious title.

THE COURT: Right. Thank you.

I'm holding in my hand now what was DMV, now in evidence as Exhibit 138, and it's limited. But the plaintiffs point out that here on the bottom and in Roman Numeral IV, and it's on Page 6 of this document, if you believe it is what it purports to be, it says "Ranbaxy's Settlement Position." Well, that's in general. I mean if that's what Ranbaxy was saying its settlement position was, you can consider that that in fact, if you believe it, was its settlement position.

Go ahead, Mr. Sobol.

MR. SOBOL: Thank you, your Honor.

The plaintiffs call Mr. Jay Deshmukh, your Honor.

THE COURT: He may be called.

MR. BALDRIDGE: Your Honor, could I just make it clear, I thought they were playing videos first, which is fine, but I don't know whether those are withdrawn.

THE COURT: Well, I don't either, but they called a witness, and that's what we're going to hear.

MR. BALDRIDGE: Yes, your Honor.

(Mr. Deshmukh enters courtroom.)

(JAY DESHMUKH, sworn.)

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JAY DESHMUKH

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DIRECT EXAMINATION BY MR. SOBOL:

Q. Good morning, sir.

A. Good morning.

Q. Please state your name and spell your last name.

A. Jay Deshmukh. Short Jay, last name is spelled "D," as in delta, "E," "S," as in "Sam," "H," as in "Harry," "M," as in "Mary," "U," "K," "H," as in "Harry."

Q. How are you today, sir?

A. Excellent. How are you?

Q. Fine. Thank you very much. I had caffeine with

my coffee unfortunately this morning.
A. Same here.
Q. Very good.
Now, you are a lawyer, sir, correct?
A. I am a lawyer.
Q. Okay. You might pull the microphone a little bit to your right so that you don't have to look this way, but you might want to turn your chair.
A. Sure.
Q. Where did you go to law school, sir?
A. Case Western in Ohio.
Q. What year did you graduate?
A. '92.
Q. At some point you became employed at Ranbaxy, correct?
A. Sorry?
Q. At some point you became employed at Ranbaxy?
A. Yes.
Q. And when was that, what year?
A. 1997.
Q. Okay. So what did you do as a lawyer between 1992 and 1997?
A. I was in private practice in a couple of law firms in Cincinnati, Ohio.
Q. Doing what kind of law?

A. Patent law.
Q. And how long did you work at Ranbaxy, from what year until what year?
A. Um, 1997 through 2009.
Q. Do you recall what month in 2009?
A. I believe it was March.
Q. And since the time you worked at Ranbaxy, where have you worked as a lawyer?
A. At my current law firm, Knobbe, Martens.
Q. Located where?
A. Well, the law firm was located primarily on the West Coast but I worked in the D.C. office.
Q. Practicing what kind of law?
A. Intellectual property law, patent law, trademark law.
Q. For about the past five years since you left Ranbaxy, correct?
A. Yeah.
Q. Okay. Now, during the years 2007, 2008 and until March of 2009, when you were working at Ranbaxy, what was your job responsibilities -- what were your job responsibilities?
A. So initially it was a -- what I would call a pure in-house intellectual property position, which means you deal with things related to patents and patent

litigation and things of that nature, including filing for patents and, um, dealing with litigations that show up. And that position then involved a little bit more into -- over time into more of a General Counsel-type role where I was dealing with more serious legal issues which came up, um, not just related to patents and trademarks, but other areas.

Q. Okay. Such as compliance matters with the FDA?

A. Um, yes.

Q. Okay. By, um -- there's -- as you've probably been made aware, there are some issues in this case regarding some transactions that began to be negotiated in the time period of July 2007, August 2007. At that point in time were you functioning basically as Ranbaxy's equivalent of a General Counsel, essentially having those responsibilities but not having that formal title?

A. I would say so.

Q. Okay. To whom did you report?

A. So you're asking at that time or?

Q. Um, yes, sir, at that time.

A. Arun Sawhney, the CEO.

Q. Okay. So you reported directly to the CEO, correct?

A. Yes.

Q. And he was based where?
A. In India.
Q. And you were based where?
A. In Princeton, New Jersey.
Q. Okay. And was that essentially your job responsibilities and the person to whom you reported in the time period, the summer of 2007, up until the time that you left Ranbaxy in March of 2009?
A. Yes.
Q. Now, you prepared for your deposition -- excuse me, for your testimony here today, correct?
A. I did.
Q. With lawyers from, um -- that are representing Ranbaxy in this case?
A. Yes.
Q. And for how long?
A. A few hours.
Q. Okay. Recently?
A. Yes.
Q. Okay. Now, I put before you what has been marked previously at this trial as Exhibit 22. Does this appear to you to be a photocopy of a submission that was made on behalf of Ranbaxy in connection with the Paragraph 4 certification that it was making for a generic Nexium?

A. (Looks.) I guess you don't want me to look through all the pages, but it looks like it.

Q. Okay. And is it fair to say that this document, which is about 105 pages or so, is a description by Ranbaxy of its position, um, with respect to 13 Orange-Book-listed patents of AstraZeneca with respect to Nexium?

A. (Looks.) So this serves, um, the notice function as mandated by the statute, and so I don't know if I could agree with that, the position of Ranbaxy with companies when they have to, um, launch or wish to launch generic products which have patents listed in the Orange Book. As a matter of course, they have to deal with the patents one way or the other. And this is, um, sort of satisfying that requirement in sending this letter out. And, um, you don't have to set out every position that you may or may not have, but you do have to deal with each one of the patents.

Q. Okay. So back at this time, and this is October of 2005, you actually signed this document, correct, sir?

A. Yes, it was a requirement.

Q. All right. And you took pride at your work at that time, correct? Yes or no?

A. I always take pride in my work.

Q. And you take pride in this particular piece of work, too, correct, sir?
A. Just like everything else.
Q. Okay. And essentially the position -- if you go to Page 2 of this document in the middle of the page where it has a 6.
MR. SOBOL: If we could have that blown up, please.
(Enlarged on screen.)
Q. Among other things this document indicates that the position of Ranbaxy is that it's providing a Paragraph 3 certification regarding three patents, the '974, the '505, and the '230, correct?
A. Yes.
Q. Okay. And that -- could you just explain to the jury what means Ranbaxy's position was with respect to those three patents?
A. Sure. Um, so what that means is because those patents still existed in the Orange Book -- and like I said one has to deal with each one of the patents which exists at the time that you do this letter, um, but they were going to expire fairly soon after the timing of this letter. We didn't feel the need to challenge these patents. And so therefore because we knew we were not going to get approval, um, and were close to well before

the patents would have expired, well before our possible approval, so therefore we filed what's called a Paragraph 3 certification which means we're not challenging these patents.

Q. Okay. And in the next paragraph, Paragraph 7, it indicates 10 patents and the position with respect to those 10 patents was a Paragraph 4 certification, correct?

A. Yes.

Q. Okay. And the position here essentially was that to best of knowledge -- to the best of Ranbaxy's knowledge, no valid and relevant claim of any of those patents would be infringed by Ranbaxy's proposed product, correct?

A. Yes.

Q. Okay. And then the balance of this 105-page document in large part describes the bases, or at least some of the bases, upon which Ranbaxy was taking that position, is that fair to say?

A. I just want to point out it says in the document itself, even if you just look at the letters, 115 pages, and so just with that slight correction. And then if you include the confidential access, it's more like 120 pages. Yes.

Q. Okay. Now, after sending this document to

AstraZeneca, AstraZeneca brought a lawsuit against Ranbaxy, correct?

A. Yes.

Q. And that lawsuit, at least at the outset, asserted five of the ten patents that had been listed in the Orange Book as having been valid and infringed by Ranbaxy, correct?

A. So the lawsuit in total, I believe, asserted six patents, but out of the Orange Book patents five were Orange Book patents out of the 6.

Q. All right. And then there was a sixth patent, the '789 patent, which was the process patent, fair to say?

A. I don't remember the last three digits of the process patent. But I'll take your word for it.

Q. Okay. And then Ranbaxy filed an answer in response to that complaint, correct?

A. I believe so, yes.

Q. And again this was a -- although you hired or someone hired lawyers to represent Ranbaxy in that case, correct?

A. Yes, I hired them.

Q. Okay. And the position of Ranbaxy, in response to the lawsuit, was that, um, each of the six patents would either be invalid or not infringed, fair to say?

A. Or both in some cases.

Q. Fair enough. Thank you.

MR. SOBOL: DMT.

(On screen.)

Q. Sir, I've put before you what we've marked as DMT. Is DMT a photocopy of a letter that was sent on behalf of Ranbaxy to Judge Pisano in connection with a potential settlement conference to be held in the summer of 2007?

A. (Looks.) Yes.

MR. SOBOL: I offer it.

MR. BALDRIDGE: Your Honor, this has already been admitted under DMV just a minute ago.

MR. BUTSWINKAS: It's 138.

MR. SOBOL: Fair enough.

THE COURT: Right, 138. Thank you, Mr. Baldridge.

MR. BALDRIDGE: Yes, sir.

Q. If you would turn to the second page, the second paragraph of that page, please.

A. (Turns.)

Q. The letter to the Court, um, in connection with the potential settlement conference states: "Nexium is AstraZeneca's follow-on product to its earlier blockbuster drug Prilosec. As Prilosec was losing its patent protection in 2001, it was a multi billion dollar per year product for AstraZeneca. To stem the dramatic

loss in sales revenue caused by the market entry of generic versions of Prilosec, AstraZeneca devised a plan to replace Prilosec with Nexium, a closely-related product containing virtually the same active ingredient in Prilosec. AstraZeneca's plan was predicated on a technique known as a, quote, 'chiral switch,' end quote."

That was a part of a position that your company took to Judge Pisano, correct?

A. I wouldn't call it a "position," but these are just stating facts.

Q. And what is a "chiral switch," sir?

A. Um, so in most -- I shouldn't say "most," many, um, medical products, drugs, um, there is the active ingredient -- every drug product has an active ingredient and the active ingredients in products which are chemically based or contain chemical compounds are organic compounds which, as they, um, occur in nature for the most part, are what is known as racemates, which means they're a 50/50 mix of, um, a compound and the other compound being a mirror image of the first compound. So this is how sort of nature, in nature you mostly find these as racemates, they're blended up naturally, they're 50/50.

Now, for the most part, only one of those two mirror

image compounds acts in your body when it goes in and it does the trick, whatever the trick is. And so what -- as the science developed in the '60s, um, chemists and drug companies, pharmaceutical companies, figured out a way of separating out the thing which actually does the job from the thing which essentially did nothing. And so, um, what brand pharmaceutical companies typically would do is to initially introduce the product which contained the mixed compound and then as, um, the patent life came to a close they would then introduce the product which contained only the active ingredient. And that sort of, if you want to call it a "technique," was -- is the chiral switch technique. And the word "chiral" has to do with chiral chemistry of what I was explaining, you know, the mirror image kind of thing.

Q. And if you would turn to Page 4 of this document, which has at the bottom right-hand corner 247, and the first paragraph of this, um, is "The legal basis for Ranbaxy's claim and defenses states as follows." "AstraZeneca's claims regarding the alleged superiority of Nexium cannot hide the fundamental reality that there is nothing new or patentable about esomeprazole. As alleged in Ranbaxy's answer, Ranbaxy intends to prove that the patents in suit are not infringed by Ranbaxy's ANDA product and/or invalid. The patents in suit are

invalid as anticipated by or obvious over several pieces of prior art."

Was this the position or a fact being stated by Ranbaxy to the Court at this time?

MR. BALDRIDGE: Objection. Compound.

THE COURT: If he can answer it, I'll allow it. Can you answer the question?

THE WITNESS: Sure.

A. Um, this was a position that Ranbaxy was taking.

Q. Okay. And then if you turn to the final page of this document, please, sir, the second paragraph.

A. The final page?

Q. It has at the bottom right-hand corner "250."

A. Okay.

Q. And in fairness to you, sir, if you look to the prior page this comes under the heading, "Ranbaxy's Settlement Position." Do you see that?

A. Yes.

Q. Okay. And then in the second-to-last paragraph, it starts in the middle, after it cites the expiration of various patents.

"Ranbaxy believes that it should be allowed to market its generic product immediately upon resolution of this case or when the 30-month stay of its FDA approval expires in May 2008."

Was that an accurate statement at that time regarding a belief of Ranbaxy with respect to this issue?

A. I wouldn't even say it's a statement of a belief because it just says what it thought it should be allowed to do.

Q. Okay. And then in the final paragraph, sir: "Ranbaxy is willing to discuss a settlement that resolves the litigation by selecting an agreed-upon date for market entry of Ranbaxy's generic product wherein the agreed-upon date is a compromise between market entry in 2008 and the expiry of the 2014/2015 patents. As Ranbaxy does not infringe the patents that expired in 2018 and 2020, Ranbaxy believes that such a settlement would account for the uncertainty to plaintiffs and Ranbaxy. Any such settlement must preserve Ranbaxy's six-month exclusivity relative to generic competition. Because Ranbaxy's six-month exclusivity blocks Teva's market entry, such a settlement would also allow Teva to obtain earlier market entry than it otherwise would have obtained."

Was that also an accurate statement of a part of a position of Ranbaxy to this court at that time?

A. (Pause.) Um, I mean this a -- what I would call a "form letter," um -- yes, this was part of a position we took when we sent out the form letter.

Q. Okay. Thank you.
Now, do you recall that you did go to a status conference between Judge Pisano in July of 2007, correct?
A. (Looks.)
Q. I don't think it's there in front of you.
But does that ring a bell, July of 2007, being the time that you went to the status conference in front of Judge Pisano?
A. It really doesn't. You know, you can tell it's been 7-plus years. But given the fact that this letter is July, I would presume that the settlement conference followed shortly thereafter.
Q. Okay. Do you recall that there was a settlement meeting in, I think, Newark in August of 2007 with AstraZeneca?
A. I remember that soon after the settlement conference with Judge Pisano, there was a settlement meeting.
Q. Okay. And do you recall -- well, is it consistent with your memory that that settlement meeting occurred on or about August 27, 2007?
A. Sir, I don't remember the date.
Q. Okay. Before you, um, went to -- (Pause.)
Before you went to the meeting with AstraZeneca in the

summer of 2007, did you speak with a man by the name of Joseph Todisco at all about the potential meeting?

A. Before the meeting with AstraZeneca?

Q. Yes, sir.

A. I don't remember speaking with Joe Todisco.

Q. Just tell the jury who he is?

A. Um, I don't remember his position exactly now, but he was somebody who worked in our business development department under Venkat, or Venkat Krishnan, who was his boss. So I didn't really deal much with him directly.

Q. Okay. Do you recall whether Mr. Krishnan or Mr. Todisco gave you some information about the amount of additional money Ranbaxy might be able to make if there were a no-authorized generic clause in a settlement with AstraZeneca for Nexium?

MR. BALDRIDGE: Objection. Foundation.

THE COURT: No, he may ask the question, does he recall it?

A. So, no, I don't recall that.

Q. Okay. I put before you CWN. It's obviously a lengthy document, sir, and it has many spreadsheets. If you just look at the memo on the front page of this. Does this refresh your memory as to whether or not there was an analysis of some value that Ranbaxy might be able to get for itself if there were a no-authorized generic

clause in an agreement with AstraZeneca for Nexium?
A. (Looks.) Obviously I'm not on this memo. It's from somebody to Joe Todisco. And, no, I don't recall ever seeing this.
Q. Okay. You can put that to the side then, sir. Okay. When you went to the meeting though in August of 2007, you did make a proposal to AstraZeneca, correct?
A. Yes.
Q. Okay. And in terms of the entry date, what's your best recollection as to what your proposal was for the entry date?
A. Um, I believe it was sometime in 2012.
Q. Okay. And do you know a man -- I'm going to probably get the pronunciation incorrect, Ahmad Aboelezz?
A. Yes.
Q. And do you recall that the month that you proposed at that meeting in August was May 2012? May?
A. I don't recall that.
Q. Okay.
A. Specifically.
Q. It could or couldn't have been, you don't remember, correct?
A. It could have been.
Q. Okay. In addition to proposing then some date in

2012, didn't you also propose that AstraZeneca provide a no-authorized generic clause to Ranbaxy that would exist for whatever period in the event that Ranbaxy was able to have exclusivity as the first-to-file at sometime?

A. So, yeah, we proposed a, um -- that only during this period of exclusivity, if we were to get it, which is to say if we ever launched a product, based on our ANDA, then we would have, um -- we would be the only generic on the market.

Q. And what you were also asking them specifically was that AstraZeneca would agree not to launch an authorized generic during a period of exclusivity that Ranbaxy might be able to have, correct?

A. Yeah, we would be the only generic on the market.

Q. And so you were proposing that AstraZeneca agree not to compete with Ranbaxy during its exclusivity period with an authorized generic?

A. We didn't say anything about competition at all. We were opening up the market. We were talking about opening up the market.

Q. Were you talking about opening up the market and allowing an authorized generic to enter the market during your exclusivity?

A. We -- had we ever gotten approval? Which I understand we still -- Ranbaxy still --

MR. SOBOL: Your Honor, motion to strike.

THE COURT: Yes, the motion to strike is allowed. Disregard it.

Listen to his questions. Answer his questions. He frames them so they can be answered "yes" or "no." Now, if you can't answer it "yes" or "no," say so.

THE WITNESS: Thank you, your Honor.

A. Um, so what was the question?

Q. The question is, isn't it fair to say, sir, that you had proposed to AstraZeneca that AstraZeneca agree not to launch an authorized generic during some period of exclusivity that Ranbaxy might be able to enjoy?

A. I've answered this question, but I'll answer it again. We propose that -- I propose that, um, Ranbaxy's product be the only generic product during its hard-earned exclusivity period of six months.

Q. Now, there was a third, um, proposal that you also made to AstraZeneca that, um, a transaction be structured so as not to -- so as to ensure that Ranbaxy's exclusivity not be forfeited. Is that fair to say?

A. I proposed that whatever agreement we came to did not accidentally or inadvertently cause the exclusivity, which we had fought for and we thought we had till then earned, be extinguished or disappear.

Q. Okay. Now, at that point AstraZeneca did not respond, correct, and there was a later meeting?
A. I don't remember those specifics.
Q. Okay. Well, do you recall that the parties met again in November of 2007, that you met with AstraZeneca again in November?
A. Yes, I do remember that.
Q. Okay. And isn't it fair to say that AstraZeneca came back with a counter proposal on the entry date and suggested -- well, May 27th, 2014?
A. Um, yes, that was their position.
Q. Okay. And isn't it also fair to say that they also agreed with the no-ag clause, the no-authorized generic clause?
A. I believe they agreed that -- with our proposal that there be no other generic other than Ranbaxy and their product during the six-month exclusivity.
Q. Including an authorized generic, that an authorized generic not be launched by AstraZeneca, correct?
A. That there would be only one generic during the six-month exclusivity period.
Q. And didn't you make a proposal about some API manufacturer and dosage-form manufacturer at that meeting in November of 2007?

A. Yes.
Q. Okay. And isn't fair to say that you actually specified that the proposal would be that 50 percent of AstraZeneca's API requirement would be furnished by Ranbaxy?
A. Yes, 50 percent of AstraZeneca's EUS API requirement, I believe it was.
Q. Okay. And you also made a proposal that Ranbaxy would provide one-third of the finished dosage form of the branded Nexium, correct?
A. Yes.
Q. And also at this meeting in November of 2007, you also raised the potential for there to be distribution agreements with Ranbaxy and AstraZeneca, correct?
A. I believe so, yes.
Q. Okay. That topic was raised in that meeting in November of 2007, correct?
A. That topic being?
Q. The distribution -- the potential for distribution agreements.
A. Yes, I believe we discussed one or two distribution agreements.
Q. Now, I put before you what's been previously marked as Exhibit 26. Is this a photocopy of a draft settlement agreement sent in connection with the

potential arrangements between AstraZeneca and Ranbaxy?
A. (Looks.) Um, yes, it looks like it's a draft attached to an e-mail.
Q. Okay. And if we go to the face page of the e-mail itself.
MR. SOBOL: Please, if you go back a page.
(On screen.)
Q. And there's an indication here in the transmittal that "We also recognize there is an ongoing review of Ranbaxy's plant in India and a discussion of a potential supply agreement which is not reflected in these draft terms."
That was what was written by Mr. Hester to your outside counsel, Ms. Fales, correct?
A. That's what it says.
MR. SOBOL: CXI, please.
(On screen.)
Q. I put before you what's been marked as CXI.
Is this, at the bottom, an e-mail transmission further in connection with these agreements between AstraZeneca and Ranbaxy?
A. (Looks.) Um, yeah, it looks like it's a string of e-mails, um, culminating with an e-mail from Jeff Pott to Ahmad and somebody else it's going to.
MR. SOBOL: I offer it.

MR. BALDRIDGE: Your Honor, I believe this was admitted as Exhibit 27. It's definitely been admitted, though.

THE COURT: Well, on that representation we'll just move on and take it as admitted.

MR. BALDRIDGE: No objection.

MR. SOBOL: All right.

MR. VAN WART: Your Honor, can we have a brief sidebar?

THE COURT: We can.

AT THE SIDEBAR

MR. VAN WART: I was concerned about all the emphasis -- I'm concerned about all the emphasis of these agreements with Ranbaxy having a prejudicial effect on Teva when the issue is that Teva is simply a -- it's a different way of getting into the --

THE COURT: I don't hear you objecting.

MR. VAN WART: I just objected. Sorry.

THE COURT: Well, I have nothing before me.

MR. VAN WART: Okay.

(In open court.)

Q. With respect to Exhibit 27, sir, isn't it fair to say that there was an ongoing discussion between Ranbaxy

and AstraZeneca regarding the potential for manufacture and supply arrangements between Ranbaxy and AstraZeneca during this time?

MR. VAN WART: Objection, your Honor.

THE COURT: Yeah, come to the sidebar.

AT THE SIDEBAR

THE COURT: Well, this serves up the issue that is now getting briefed. I'm reading the various things that have been filed.

The Court has ruled -- well, I will tell you, cases are a living thing, and when you hear the evidence, um -- I think I'm anticipating the argument this afternoon. So let me start there.

The more I hear the evidence in this case the less I think this case is about substantive patent law, and so striking so much of McCool's testimony as I have, but retaining McGuire's testimony, does not mean that the case is dead, and I'm very much looking forward to the arguments this afternoon. But having said that, I've ruled that Ranbaxy caused no antitrust damages.

The plaintiffs keep trying to get into Ranbaxy. All I see that's alive for Ranbaxy is did Ranbaxy conspire with AstraZeneca to prevent the entry prior to March 27th, 2014, of the generic? If there's enough

evidence to get to the jury on that, Ranbaxy -- we'll see what the jury says. But I'm not interested, as a matter of law, in whether there was any payment from AstraZeneca to Ranbaxy. I'm not interested in had there not been a payment, Ranbaxy would have done this, that or the other thing, they would have gotten on the market, therefore the contingent entry for which Teva negotiated would have allowed Teva to get on the market, which is at issue in this case. The question is only conspiracy.

So I have been listening to this, but informed by these briefs, I think much of this is irrelevant, and I'll hear you.

MR. SOBOL: Thank you, your Honor.

The Teva case requires that we prove, among other things, that Teva would have gotten entry earlier.

THE COURT: Yes, I agree.

MR. SOBOL: Right. A part of our proof, in regard to that, is that once the Ranbaxy date is moved up in time, from May 27th, 2014 to some earlier point, in an alternative settlement, that is also the date that Teva would have had as well.

THE COURT: I think --

MR. SOBOL: If I may? If I may? It's quite serious.

THE COURT: Indeed it is. It's key.

MR. SOBOL: Yes, it is.

Now, the evidence to date, quite clearly from both Mr. Hester and from Ms. Julie -- Ms. Julie was actually quite emphatic about it.

THE COURT: Oh, I have it very much in mind, "I would lose my job."

MR. SOBOL: "I would lose my job if there was any date that was earlier."

THE COURT: I do listen.

MR. SOBOL: I understand that. I don't think I profess to provide any new information in an argument, your Honor.

THE COURT: Right.

MR. SOBOL: But this is my position, your Honor. The plaintiffs, I think you know very clearly, we intend to prove that we don't have to go down into any kind of payment or Actavis issue with Ranbaxy and AstraZeneca. That's not the direction we're going.

THE COURT: Right. Well, you're not. But okay.

MR. SOBOL: I'm not. Understand what I'm doing is I'm going to show that there's an agreement between these two companies that is laden with payoffs and which if those payoffs did not exist, the Ranbaxy date would be earlier, and therefore so would Teva's be.

THE COURT: Yeah.

MR. SOBOL: I have in mind one thing, your Honor. There were some documents produced to us yesterday pursuant to your order, okay, and one of those documents, a communication between Mr. Hester and Mr. Pott, makes vividly clear that the two of them knew that providing this no-AG clause to Ranbaxy meant that they were getting a later date from Ranbaxy. And if that no-AG clause hadn't existed, then the date would have been earlier, and it would have been earlier for Teva.

THE COURT: Yeah, but what you have to prove, where you and I -- again I'm only thinking as to what your -- what you must prove here. I take no position.

MR. SOBOL: Uh-huh.

THE COURT: I think you've got to show that Teva would have gotten into a deal with Ranbaxy, given their exclusivity, since Ranbaxy couldn't come to market and would have then come to market were it not for the AstraZeneca-Teva deal. That's how, when I come either this afternoon or the close of -- well, this afternoon is a large and unjustified payment. They'll certainly attack you at the end of the case. Absent enough evidence that they would have gotten into a deal, I'm going to direct.

MR. SOBOL: Sure.

THE COURT: Now, the business about whether Teva's date would have been moved up to me is immaterial in light of my rulings because Teva could never bring that thing to market, which seems in accord with --

MR. SOBOL: You mean Ranbaxy.

THE COURT: I do mean Ranbaxy. I'm sorry. Yeah.

MR. SOBOL: I'm searching quite honestly, your Honor, where the miscommunication may be, because I honestly think there's a miscommunication on my part. Here's the thing.

What you just indicated is that we will have to prove that there also had been a deal between Ranbaxy and Teva. We intend to obviously prove that. But the question is toward what end? In other words --

THE COURT: Well, they would have cut some deal that they then would have brought to Teva, who could do it arguably, and come to market.

MR. SOBOL: But then when is the point? If I'm not able to prove that the date would have been earlier for Ranbaxy --

THE COURT: Well, let me do it this way. I'm delighted to know that you plan at least to rest by next Tuesday.

(Laughter.)

THE COURT: Oh, I'm very delighted.

(Laughter.)

THE COURT: Now that being said, it may be more of a proof thing that you're hung up with me. Now, Mr. Van wart is raising these relevant objections. You prove the potentiality of a deal and you'll have greater leeway -- I make no promises naturally, in demonstrating to me that this would have been advantageous to Ranbaxy because they would have, um, because of these other things, had some sort of earlier date.

MR. SOBOL: Your Honor, this witness is --

THE COURT: Well, I'm missing it. I mean Mr. Baldridge is shaking his head, but he's an advocate. As the presiding judge, I don't know what we're doing here, and I'm supposed to be taking notes not only as I do for the trial, but up until five minutes from now, I've got my class, and one of the notes I have written to my class is that much of this seems irrelevant. I'm missing it.

I was interested to hear this and some of the things I'm interested in, but much of it seems irrelevant. That if we had a Ranbaxy-Teva deal, the potentiality of it, supported by expert testimony from the documents or however way you can do it, then maybe I would be more liberal.

MR. SOBOL: Maybe I'll -- I'll make this suggestion, your Honor, which I think is a little bit odd, because I can't do anything better obviously.

THE COURT: It's never odd. We'll drop him and you can bring him back.

MR. SOBOL: We'll drop him and we'll go to Professor Rosenthal.

THE COURT: Go to wherever. I'm much more interested in him. But it isn't what I'm interested in. I'm managing the trial. You've lost me on him. I'll let him step down -- I mean I've got to let them now ask some questions. Maybe they'll open up things. Maybe they won't. But I'm not getting it.

MR. SOBOL: As long as I can bring him back?

THE COURT: You can bring him back.

MR. SOBOL: Okay.

(In open court.)

MR. SOBOL: Your Honor, in light of the colloquy at sidebar, the plaintiffs would like to suspend their inquiry of this witness at this time and reserve the right to recall him at a later point in the trial.

THE COURT: And I would allow that. In fairness, I will allow complete cross-examination if he's recalled, but I can't just let him go before asking you

whether you want to examine him at this time, the defense? So if he comes back, you get complete cross-examination. If he doesn't, he doesn't. But you tell me. And so -- unfortunately I don't have a list. You've been very good at giving me lists.

Oh, I do have a list?

(Pause.)

THE COURT: Oh, I do have a list. I stand corrected. Here it is. Thank you very much.

So, Mr. Baldridge, I'll ask you first?

MR. BALDRIDGE: Sir, we will not cross-examine him at this time.

THE COURT: Not now anyway.

Mr. Gaffney, at this time?

MR. GAFFNEY: We will reserve.

THE COURT: And Mr. Van Wart at this time?

MR. VAN WART: Yes, your Honor.

THE COURT: So that's reserved.

You may step down, sir, subject to recall.

You may call your next witness.

MR. SHADOWEN: Your Honor, the plaintiffs call Professor Meredith Rosenthal.

THE COURT: He may be called.

(Pause.)

THE COURT: She may be called. Forgive me, ma'am.

I met our new next-door neighbors the other day and they have a daughter named Meredith and I should have done better.

(MEREDITH ROSENTHAL, sworn.)

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MEREDITH ROSENTHAL

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THE COURT: And it's an opinion witness, so, yes, may I have the report.

DIRECT EXAMINATION BY MR. SHADOWEN:

Q. Professor Rosenthal, would you state and spell your name for the jury, please.

A. My name is Meredith Rosenthal, M-E-R-E-D-I-T-H, R-O-S-E-N-T-H-A-L.

Q. And am I right that you're here to testify regarding one of the questions on the verdict slip that is having to do with market power and the relevant market?

A. Yes, I am.

Q. What do you do for a living?

A. I am a professor of health economics and policy at the Harvard School of Public Health where I am also an

Associate Dean.

Q. And what positions do you currently hold at Harvard?

A. At Harvard I'm on the faculty in the Department of Health Policy and Management where I teach, advise students, and do research, and I also serve as the Associate Dean for Diversity to improve our recruitment of all kinds of students and faculty and ensure their success at the school.

Q. And what courses have you taught at the school?

A. I have taught a number of courses over the years including mental health policy in the U.S. I currently teach a course on the economics of health policy in the U.S. context. I have also taught a course on the quality of care. That last course I taught at Harvard College for undergraduates. My other teaching typically involves master students and doctoral students in health policy.

Q. Is your own PhD in economics?

A. My PhD is in health economics. Help economics is an applied field of microeconomics and my training involves essentially all of the same coursework as a PhD in economics with the exception of macroeconomic theory, which is how the economy works as a whole, and in addition to that I have studied the specifics of health

policy, institutions, and the public policy process.
Q. In your academic work do you have particular research interests?
A. Yes, I do. In my academic work, as you can tell from the courses I teach, is focused on U.S. health policy and in particular I'm interested in the economics of U.S. health policy institutions including those in the pharmaceutical industry and in health care delivery and financing.
Q. And do those research interests include the economics of pharmaceutical markets?
A. Yes. My research interests include a number of specific topics in pharmaceutical economics including the use of formularies and benefit designs and how that affects the sales of prescription drug products and the total cost of prescription drug care. I have also done substantial work on marketing pharmaceutical products.
Q. Have you published any articles?
A. Yes, I have. I have published more than 50 peer-reviewed articles, many of them in medical journals such as the "New England Journal of Medicine," the "Journal of the American Medical Association," as well as book chapters and commentaries.
Q. And have you done editorial work for journals?
A. I am currently serving on an advisory board for

the New England Journal of Medicine for a specific series that they publish, a perspective series. I've also served on the editorial board of the Journal of Medical Care Research and Review. And like most academics I serve as a peer-reviewer for a wide range of journals reviewing the work of my peers at least once or twice every month.

Q. Am I right that you have won an award from the Alfred P. Sloane Foundation?

A. Yes, I was an Alfred P. Sloane industries studies fellow for my field work in health economics.

Q. And are you a member of the Massachusetts Public Health Council?

A. Yes, I am an appointed member of this council that advises the Commissioner of Public Health in Massachusetts as well as the Governor on important public health issues such as the current concern about Ebola, new vaccinations, a wide range of public health issues, and this body also promulgates regulations for the Department of Public Health.

Q. All right. Am I right that you're also an affiliate of an entity called Greylock McKinnon Associates?

A. Yes, I'm an academic affiliate of Greylock McKinnon Associates. Greylock McKinnon Associates is a

consulting firm and a litigation support firm. They have economists who work with them, like me, on matters such as this one.

Q. In connection with your work with Greylock, have you testified in antitrust cases regarding the efforts by brand manufacturers to delay generic entry?

A. Yes, I have served as a testifying and consulting witness in many such matters.

Q. And in connection with that work have you become familiar with generic erosion curves and the competitive features of the pharmaceutical industry?

A. Yes, one of the most important features of the pharmaceutical industry relates to the role of generics and as noted these generics cause brand name products to lose a great deal of their sales. That's what we mean by a generic erosion curve. These curves have been the subject of my work in all of these matters.

Q. Have you ever testified before Congress on health economics subjects?

A. On two occasions I've testified in Congress, um, one of which related to pharmaceutical policy. In particular I have done some research, as I mentioned earlier, on pharmaceutical marketing with a specific focus on the impact of direct-to-consumer advertising. I was called to a Congressional hearing to advise a

committee on the effectiveness of direct-to-consumer advertising and its public health effects.

Q. Okay. And at my request did you prepare a CV or a resume?

A. Yes, I did.

Q. I put before you what's been marked for identification as FHA and ask you if that's your resume?

A. Yes, it is.

MR. SHADOWEN: And, your Honor, we move its admission.

THE COURT: No objection?

MR. BALDRIDGE: No objection, your Honor.

THE COURT: It may be received, Exhibit 139.

(Exhibit 139, marked.)

Q. Professor Rosenthal, are you being compensated for your work on behalf of plaintiffs in this case?

A. Yes, I am.

Q. At what rate?

A. My current rate is $625 an hour.

Q. And what was your assignment in this case?

A. I was asked to offer an opinion about the extent to which the defendant, AstraZeneca, possesses market power for the drug Nexium and also what the relevant market is for considering that market power.

Q. And you reached a conclusion on those?

A. Yes, I did.
Q. Okay. And what materials did you rely upon in reaching your conclusions?
A. My conclusions are based on my review of the economic literature and specifically the institutions and economics of the pharmaceutical industry, my review of defendants' documents that were provided in this matter, and my analysis of standard industry data that demonstrate what happens when generic entry occurs in the pharmaceutical market. I use established economic analytical methods to examine those data and come to my opinions in this matter.
Q. Okay. What methodology did you use in reaching your conclusions?
A. The methodology I used involves analyzing pricing and quantities of prescription drug products and in particular those in the PPI class that I imagine you've been hearing about, and my analysis uses an established approach which gets at the question of market power by examining what happens to a product's sales when a potential competitor's price decreases in relative terms.
Q. We'll get to it in all kinds of detail, but in very summary form, very briefly, what conclusions did you reach?

A. Analyzing the market conditions and institutions here and the data that I describe in my report, I concluded that the defendant, AstraZeneca, possessed market power for Nexium and continues to do so and that the relevant market for antitrust analysis is Nexium and its AB-rated generic.

Q. Okay. Let's start at the beginning. What is "market power"?

A. "Market power" essentially translates into the ability of a firm to be able to maintain prices above competitive levels. "Above competitive levels" simply means that the price is much higher than the production cost of the product.

Q. And does having market power mean that a manufacturer can charge whatever it wants for its product?

A. No, under no circumstance that I know of in economics can a firm charge whatever it wants. Even a firm that is the unique, the sole supplier, a true monopolist as it were, has to consider the following trade-offs. If I raise my price by some amount, that will increase the margin on each unit I sold, but if I do so I may lose some customers. And so there is always that tension. And even a monopolist, that is the sole supplier, will eventually settle on a price where the

trade-offs between the quantities lost, because the price is very high, and the additional margins, on each unit. So that results in a market price, not an infinite price.

Q. So what is a "relevant economic market"?

A. The "relevant economic market" is the smallest market that a firm could control and be able to maintain these prices that are significantly above the marginal cost of producing the product. So --

THE COURT: Well, I interrupt only to ask a question.

What about profit? Any firm is entitled to make a legitimate profit, aren't they?

THE WITNESS: Yes, your Honor, absolutely.

THE COURT: So how does that work into your approach here?

THE WITNESS: Absolutely. May I?

THE COURT: That's my question.

THE WITNESS: Thank you.

A. That's absolutely right, any firm is entitled to make a profit, and market power is not to suggest that the firm is not entitled to make that profit. The question is whether a firm can raise prices to supercompetitive levels and still be profitable in doing so? And that in and of itself translates into this idea

of market power. If there are many substitutes for a product available, a firm will not be able to maintain prices that are as high, right, because consumers will substitute away and they would lose profits. So when we observe these high profits, an economist would approach that and conclude that the substitution away from the products at these high prices is minimal enough that high prices are still profitable.

Q. All right. When you say "substitute away," do you mean buy something else?

A. Substitute away from a product could be buy something else, it could also be to not buy anything at all.

Q. Okay. And just so we can get into the details of the particular characteristics in the pharmaceutical industry, can you first describe for us how competition works in a typical market?

A. Sure. Absolutely.

So the idea of competition, as I began to say, involves having multiple products that may substitute for one another. So we have firms in a competitive situation that offer products that can be used by consumers for the same purpose. And then competition really is all about demand. And so products compete more closely with one another to the extent that the buyers view those

products as interchangeable. And that's not a theoretical concept. When economists look at competition, they look at actual consumer behavior and in particular competition is borne out by the idea that small changes in price from a competitive level lead to greater shifts in quantities. So the loss of sales that I indicated later -- earlier would follow from a competitive situation. If a product finds that it cannot increase its price by a small but significant amount without losing all of its sales, then that suggests that there's competition in that marketplace.

Q. All right. Can you help us out by giving us -- saying all of that with an example, sort of teach us through an example.

A. Sure.

So if you walk in the potato chip aisle of the grocery store you see many alternatives, many different brands and styles of products and consumers will go to the store looking for a potato chip, for example, and see all the alternatives. And one important piece of the demand that I referred to earlier is the idea that consumers have preferences. In my house we like salt and vinegar chips and we're not crazy about those kettle chips. And so I have my preferences and those preferences determine the extent to which I'm willing to

substitute one product for another, one chip for another. So it may be that the price of my favorite chip goes up by a little bit. And I don't think that some other chips on the row are as good and so that small price change doesn't cause me to change my behavior. But a larger price change might cause greater substitution across alternatives.

And so when we think about competition, these are the kinds of questions we're asking, to what extent do consumers really substitute across products in the face of small relative price changes that are sustained? A particular product will have market power if it's able again to raise its product above other prices.

For potato chips, we think people in the supermarket are pretty good at looking at those prices, which by the way are marked on the bags and on the shelf, and they make those trade-offs, they're price-sensitive enough that you'll see that most of those bags of potato chips have a very similar price because they do in fact get substituted for one another fairly rapidly.

Q. Now, this competition between prescription drugs that are in the same therapeutic class don't necessarily follow this consumer preference, you know, the price model that you just described?

A. Right, so there are a lot of clear differences

between a standard consumer good and a prescription drug. First of all, we don't just walk into the pharmacy, get behind the pharmacist's desk, and look at those prescription drugs and decide which one to buy. Moreover, we don't really have preferences for prescription drugs in the same sense that we have preferences for potato chips. We come in with a symptom or a problem that we've seen a physician about and we rely on the physician to not only tell us the nature of our problem but also what kind of therapy might help us. And so a couple of things that I've just pointed out there is that consumers don't directly buy prescription drugs, they also don't choose them in the same way that they choose other products, they rely on their physician's advice to a large degree. Not that consumers have no role to play, but at the very least there needs to be a dialogue between the physician and the patient.

The other thing is that patients don't usually pay the full price of their prescription drugs. So unlike in the grocery store when it's my wallet, my money that's going to pay for the potato chips and I see the price marked on them, that's not what happens at the pharmacy, right? The insurance company has a price that it pays and the pharmacy -- the pharmacy directly bills

typically a PBM, which you may have heard about. The patient really just sees their co-payment. So the patient doesn't really know the full price, doesn't typically bear the full price.

And the physician, the key decision-maker, as far as health economics is concerned, the physician typically knows very little about price differences across prescription drugs. And in fact it would be nearly impossible for the physician to anticipate what is actually going to be paid at the pharmacy for a given product because those prices are outside of the physician's realm.

And then finally just to emphasize the role of insurance. So most of us get our prescription drugs under a health insurance plan. There are certain contingencies that we're required to follow under those plans. And in particular, there are co-payments that are associated with what's known as a "formulary," that is a list of preferred drugs for a health insurer.

So very different market structure than typical consumer goods. And many aspects of this market mean that price is not very clear to the decision-makers, the patient and the doctor, and therefore we expect price competition specifically to be attenuated.

Q. And by "attenuated," you mean less than usual?

A. Yes, by "attenuated" I mean less than usual. It's very hard for physicians and patients to shop for the lowest-price alternative. It's hard to even get that information.

Q. So you've contrasted for us sort of the demand characteristics, the consumer preferences side of the equation, in the typical market and then in the pharmaceutical industry.

Are there any unique characteristics of the pharmaceutical industry with respect to suppliers, on the supply side?

A. As we've been hearing about today there are important FDA rules that govern entry into the pharmaceutical market. Brand name drugs have to go through a process to get their products approved, and by law, by statute, those products are granted a period of exclusivity during which there can be no other chemical entities that are exactly the same that can come on the market. So no generic entry is permitted for a period of time.

That law, which was enacted by the Hatch-Waxman Act in 1984, essentially is a way of making sure that innovative firms are protected for a period of time so that they can earn extra profits to help them recover their research and development costs. And so that

structure of the market is an important feature. Another structural or institutional feature of the market is a set of policies that relate to the ability of a pharmacist to substitute one product for another. So if you go to the pharmacy with a prescription for a brand-name drug, the pharmacist is allowed to -- with slightly different considerations across different states, but in effect is allowed to substitute an AB-rated, that is a bioequivalent generic version of that product, automatically, or after notifying the patient in some states, but that pharmacist cannot substitute any other product for that prescription. So the prescription can only be substituted at the pharmacy for another product when an AB-rated generic exists. And so that's a really important mechanism in this market that ensures that generic substitution happens much more rapidly than any other kind of substitution.

Q. (Pause.) Now, let's turn to the precise question regarding the definition of a relevant market in this case. What are the possibilities?

A. There are essentially two possibilities to consider. One possibility would be the therapeutic class of proton pump inhibitors, the PPIs, that would be the large market in which Nexium may be considered to exist. The other possibility is the chemical entity,

what I might use as shorthand, "the molecule," so it's esomeprazole magnesium. So those are the two -- the two likely markets to consider.

Q. How did you go about figuring out which one was right?

A. I used the standard economic approach, as I noted earlier, to examining data that would allow me to understand the extent to which Nexium's sales would respond to changes in price of these hypothetical competitors, that is other PPIs or its own AB-rated generic.

Q. Is that a standard test in economics for defining a "relevant market"?

A. Yes, this is a textbook approach in antitrust analysis in economics.

Q. And it's sometimes known as the "SSNIP test"?

A. Yes, in its formal version it's known as the "SSNIP test."

THE COURT: Standing for what?

THE WITNESS: Standing for "Small but Significant Nontransitory Increase In Price." I was trying to spare you that.

(Laughter.)

Q. Now, economists sometimes look to what are known as "natural experiments" in order to make judgments

about which products are in which markets?
A. Yes, very commonly economists rely on natural experiments and indeed that is the most common approach to examining these questions of market definition.
Q. Can you explain to the jury briefly what you mean by a "natural experiment"?
A. Sure. Well, the jury no doubt knows what an experiment is, we think about scientists in their laboratories under controlled conditions conducting an experiment to understand how the world works in some way, a biological mechanism, for example. Economists, because our laboratory is the economy, the market, we don't get generally to run experiments, in some exceptions we do, but for the most part we look for policy changes or other kinds of market events that alter something, a price -- very commonly and that's what we'll talk about here, alter something suddenly and then we can study what effect that has on quantities.
Q. And did you do that here?
A. Yes, I did.
Q. All right.
MR. SHADOWEN: Scott, can we see Figure 4, please.
(On screen.)
Q. Professor Rosenthal, can you describe for us what it is we're seeing here.

A. Figure 4 shows Nexium sales over its life cycle, from its entry in early 2001 through the end of my data, which is January of 2013.

MR. SCHMIDTLEIN: Your Honor, may we approach?

THE COURT: You may.

AT THE SIDEBAR

MR. SCHMIDTLEIN: She obviously has a lot of slides she's about to use that are based upon data that's not in the record at this point. Our point only is she can rely on it, it may be data that an expert can rely upon, but the data itself is not in the record. I guess I'd like some instruction to the jury that --

THE COURT: Well, now, wait a minute. I've read your briefs here and, um, without being specific, you accurately state the law. I'm not going to let her throw up slides that show IMS data because while she can rely on hearsay, that doesn't make the hearsay admissible. This one they have no objection to because this is in her report.

I'm not troubled by the timing of things with this expert. So those things that have been disclosed can be shown. But I don't see any need. You can object if she starts testifying to the hearsay and I'll sustain it. I don't give advisory opinions, but as an attempt to give

guidance, that's what I think.

MR. SCHMIDTLEIN: All these, like the chart they've got up now, these are all based on IMS data.

THE COURT: Well, of course, and if we're wondering, so that you have an adequate record, I rule, on the basis of the record that we have so far, that an expert such as this may rely on IMS data.

MR. SCHMIDTLEIN: Thank you.

(In open court.)

THE COURT: Go ahead, Mr. Shadowen.

Q. So you were explaining this, it shows the sales of Nexium over its life cycle and it's based on IMS data. Can you explain to the jury what IMS data is?

A. The data that were used to construct this chart come from a company called IMS Health, they're a data collection and consulting firm that produces a series of data says that allows us to examine what happens in prescription drug markets product by product. So these data in particular come from retail pharmacies, they are directly drawn from the cash registers of a network of pharmacies that allows IMS Health to make calculations month by month about the specific sales and prices for all of the prescription products on the market.

THE COURT: But just so I'm clear. That may be

what IMS data is, and you say people in your field rely on it, is that right?

THE WITNESS: Yes, your Honor.

THE COURT: So you use it. But this chart we're looking at here, you, and I won't say "made it up," but you created it for the purposes of your analysis to assist in giving testimony here?

THE WITNESS: Yes, your Honor, and may I clarify? The chart in particular uses data from IMS Health.

THE COURT: To the jury.

THE WITNESS: Excuse me.

A. The chart in particular uses data from IMS Health directly. So they would provide us and they did provide us with a spreadsheet with the numbers that are plotted on this chart. There were no calculations to come to those numbers. This is a graphing of the raw data from IMS Health.

THE COURT: Go ahead, Mr. Shadowen.

Q. And is IMS data, in particular the transactions of the sales data here that we're looking at, the kind of data that you routinely rely upon in your academic work?

A. Yes, I have published numerous articles based on IMS Health in the New England Journal of Medicine and other venues as many other experts in my field have done as well. I have also used these data to testify in

cases such as this one. And furthermore I understand that pharmaceutical manufacturers use IMS Health data for strategic and tactical purposes as well.

MR. SHADOWEN: Scott, if we could go to the next one, please.

(On screen.)

Q. Show us, if you could then walk us through -- you referred to the SSNIP test and natural experiments, can you walk us through this data in this chart and explain to us the application of the SSNIP test in the natural experiments that you referred to?

A. Okay, so the SSNIP test that I'm going to walk you through will have a number of parts, this chart is going to be the first part, and in this part in particular we're going to look at a series of market events and what effect they appear to have in our data on the sales of Nexium over time.

THE COURT: Well, if you're going to do all of that, it's time for a recess, and we'll start doing it in -- short recess, because I started at 9:30, only 15 minutes.

Keep your minds suspended. Do not discuss the case either among yourselves, nor with anyone else.

You may stand in recess for 15 minutes. We'll return at 11:15 and continue.

We'll recess.

(Recess, 11:00 a.m.)

C E R T I F I C A T E

I, RICHARD H. ROMANOW, OFFICIAL COURT REPORTER, do hereby certify that the foregoing record is a true and accurate transcription of my stenographic notes before Judge William G. Young, on Wednesday, November 12, 2014, to the best of my skill and ability.

/s/ Richard H. Romanow 11-12-14

RICHARD H. ROMANOW Date